NOV 27 2013

510(K) Summary

This summary of 510(k) information is being submitted in accordance with the requirements of 21 CFR 1040.10 & 1040.11

1. General Information

Submitter: Genesis Biosystems, Inc.
1500 Eagle Court
Lewisville, TX 75057
972-315-7888 (direct)
972-315-7818 (fax)

Contact Person: Jim Lafferty
President
Genesis Biosystems, Inc.
1500 Eagle Court Lewisville, TX 75057
jgroves@genesisbiosystems.com

Manufacturing Facility: Genesis Biosystems, Inc.
1500 Eagle Court
Lewisville, TX 75057

Summary Preparation Date: 15-April-2013

2. Names

Device Name: Genesis LED Device
Common Name: Laser instrument, surgical, powered
Regulation: 878.4810
Product Code: GEX

3. Predicate Devices

Revitalight Skincare System (K042630)
Lightwave Deluxe (K082586)

4. Device Description

The Genesis LED Device uses high-end Light Emitting Diodes (LED's) to distribute the specific wavelengths of light it uses. This technology is commonly referred to as Photobiostimulation, Light Emitting Diode Therapy (LEDT), or LED's. The application of LED's to tissue is non-invasive.
The Genesis LED Wands emit light at the following wavelengths:

Device:	Wavelength:	Output:
Genesis LED Wand RED	627 nm	135mW/cm², pulsed 50% duty cycle
Genesis LED Wand BLUE	415 nm	135mW/cm² pulsed 50% duty cycle

5. Indications for Use

LED Color	Wavelength	Indication:
Red	627nm	Generally indicated for use in dermatology for the treatment of superficial, benign vascular and pigmented legions
Blue	415nm	Generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris

6. Performance Data

Based upon an analysis of the overall performance characteristics for the device, Genesis Biosystems, Inc. believes that no significant differences exist between the Genesis LED Wands and the predicate devices referenced in this document.

7. Comparison to Predicate Devices

Decision Process	Decision	K042630	K082586
Does new device have same Indication Statement (as marketed device?	Yes. The Genesis LED Wand device has the same intended use as predicate devices noted.	The RevitaLight Skin Care System generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris (Blue Pulsars)	The LightWave Deluxe Red light is indicated for use in dermatology for treatment of superficial, benign vascular, and pigmented legions. (Red Pulsars)
Does new device have same technological characteristics, e.g., design, materials, etc?	Yes. The Genesis LED Wand device has the same technological characteristics utilizing light emitting diodes, a power source and means of controlling both.	Base unit contains power supplies and control unit. Pulsator attachments contain the light emitting diodes and connect to the base unit.	The base unit contains the power supplies and the control unit. The LED panel is attached to the end of the arms and then positioned for patient treatment.
Are the descriptive characteristics precise enough to ensure equivalence?	Yes. The devices are sufficiently characterized to ensure equivalence.	Operates as blue (420nm), yellow (590nm), and red (625nm) LED source at 80mW/cm^2. LED array panel hand held device.	Operates as red (630nm to 830nm) LED source at 4.73J/cm^2.
Performance data demonstrate equivalence?	Yes. The device performance demonstrates equivalence.	Operates equivalently as yellow (590nm) and red (625 nm) LED source.	Operates equivalently as a red (630nm-645nm) LED source.

8. Testing

Performance data in the form of clinical trials were not necessary as the device uses the same technology and intended use as the predicate devices.

Testing information demonstrating safety and effectiveness of the Genesis LED wands in the intended environment of use are supported by testing that was conducted in accordance with the following standard(s): ISO 14971: 2009

Biocompatibility testing was not performed as the Genesis LED Wands do not make contact with the skin at any time before or during treatments.

Testing to demonstrate compliance to the recognized electrical safety and EMC requirements of IEC 60601-1 and IEC 60601-1-2 have been performed by an independent, accredited laboratory.

Testing to determine laser classification according to IEC 60825-1 was performed by an independent, accredited laboratory.

9. Conclusion

Based upon an analysis of the overall characteristics for the device in comparison to the predicates, Genesis Biosystems, Inc. concludes that the Genesis LED Wands are substantially equi

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Genesis Biosystems, Incorporated
Mr. Jim Lafferty
President
1500 Eagle Court
Lewisville, Texas 75057

November 27, 2013

Re: K131142
Trade/Device Name: Genesis LED Wands
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: October 16, 2013
Received: October 17, 2013

Dear Mr. Lafferty:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joshua C. Nipper -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131142

Device Name: Genesis LED Wands

Indications For Use:

Led Color	Wavelength	Indication:
Red	627nm	Generally indicated for use in dermatology for treatment of superficial, benign vascular and pigmented lesions
Blue	415nm	Generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Joshua C. Nipper -S